Research Information Bulletin

SUBJECT RECRUITMENT

Several recruitment issues can be problematic for investigators because they involve money. The following policies and guidelines should be considered when designing a research protocol.

Payment To Subjects

VA policy prohibits paying patients to participate in research when the research is an integral part of a patient's medical care and when it makes no special demands on the patient beyond those of medical care. Payment may be permitted, with prior approval of the Human Studies Subcommittee, in the following circumstances:

1. *No direct subject benefit*. When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice in affiliated, non-VA institutions is to pay patients in this situation.
2. *Others being paid*. In multi-institution studies, where patients at collaborating non-VA institutions are to be paid for the same participation in the same study at the same rate.
3. *Comparable situations*. In other comparable situations in which, in the opinion of the IRB, payment of volunteers is appropriate.

Prospective investigators who wish to pay research subjects shall indicate in their proposal the justification for such payment with reference to the criteria listed above, and in addition shall:

1. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject;
2. State the terms of the subject participation agreement and the amount in the informed consent document; and,
3. Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the veteran patient to volunteer for the research study.

Payments to subjects should be placed upon a schedule and prorated based upon the level of participation to date. Payments must not be contingent upon completion of the study.

The IRB and R&D Committee will review all proposals involving the payment of subjects (in excess of reimbursement for travel).

Advertisements

All advertising plans and materials for subject recruitment must be reviewed by the IRB.

Advertisement information should include the following:

1. The name and address of the investigator;
2. The purpose of research or condition being studied;
3. Summary of eligibility requirements;
4. Incentives (i.e. payments) and benefits for participation (if any);
5. Location for research and whom to contact for more information; and
6. Time commitment required for participants (if appropriate).

Advertisement materials should:

1. Not be misleading to subjects;
2. Not make any claims of efficacy, safety, equivalency, or superiority if investigational drugs or devices are involved;
3. Not overemphasize payment;
4. Not overstate benefits or imply favorable outcomes beyond what is outlined in the consent document and protocol; and,
5. Not be coercive or use undue pressure.

Compensation to Researchers for Enrollment

Compensation to investigators, physicians or other healthcare providers for identifying and/or enrolling subjects will not be allowed. Incentives include payments from study sponsors to research institutions or individuals for purpose of increasing the numbers and/or rate of subject enrollments. Such incentives include monetary payments, reimbursements for travel, or other expenses that may or may not be related to the study. Finder's fees (i.e. payment to physicians or others for referring subjects) and bonus payments (i.e. payments to investigators, study coordinators or institutions for enhanced enrollment [beyond actual costs]) are not acceptable.

Additional cost payments (i.e. payment that is based on additional costs for enrollment beyond what was originally planned) and additional per-subject payment for increased costs associated with enhanced and/or accelerated enrollment or additional procedures, may be acceptable. These matters should be reviewed by the R&D Committee.